187 (2)

No. 10-1070

IN THE

# Supreme Court of the United States

EISAI CO. LTD AND
EISAI MEDICAL RESEARCH, INC.,

*Petitioners,*

*v.*

TEVA PHARMACEUTICALS USA, INC., through its
GATE PHARMACEUTICALS Division,

*Respondent.*

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

## BRIEF IN OPPOSITION


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## RESPONDENT TEVA'S RULE 29.6 STATEMENT

Pursuant to this Court's Rule 29.6, counsel for respondent Teva Pharmaceuticals USA, Inc. certifies that respondent Teva Pharmaceuticals USA, Inc. is an indirect wholly owned subsidiary of Teva Pharmaceutical Industries Ltd. through the following parent companies: (i) Orvet UK Unlimited (majority shareholder), which in turn is directly owned by Teva Pharmaceuticals Europe B.V., which in turn is directly owned by Teva Pharmaceutical Industries Ltd; and (ii) Teva Pharmaceutical Holdings Cooperatieve U.A. (minority shareholder), which in turn is directly owned by IVAX LLC, a direct subsidiary of Teva Pharmaceuticals USA, Inc. Teva Pharmaceutical Industries, Ltd. is the only publicly-traded direct or indirect parent company of Teva Pharmaceuticals USA, Inc. and no other publicly traded company owns more than 10 % of the stock of Teva Pharmaceuticals USA, Inc.

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As requested by this Court, Respondent Teva Pharmaceuticals USA, Inc. ("Teva") hereby responds to a petition for a writ of certiorari filed by Petitioners (collectively "Eisai"). This Court should deny the Petition because there is no longer any case or controversy under Article III of the Constitution to resolve the question presented by Eisai for review. Because of the particular circumstances presented here, whether or not this Court directs the Federal Circuit to vacate its judgment in this litigation can have no practical impact on the parties. Eisai therefore lacks standing to seek this Court's review. The Petition invites this Court to assume jurisdiction to render a mere advisory opinion. This Court should decline that invitation.

## COUNTERSTATEMENT OF THE CASE

The procedural history of this case is complex but largely immaterial for purposes of deciding whether to grant the Petition. The essential facts are these.

Eisai sells Aricept®, a drug used in the treatment of Alzheimer's Disease. The active ingredient in Aricept® is the compound donepezil. In its New Drug Application to sell Aricept®, Eisai identified five patents that it claimed covered either donepezil or methods of using it, as required by 21 U.S.C. §355(b)(1). One of those patents, U.S. Patent No. 4,895,841 (the "'841 patent"), covered donepezil itself. The other four patents covered either different crystalline forms (or "polymorphs") of donepezil or pharmaceutical formulations that contained donepezil. The FDA listed those five patents in the publication *Approved Drug Products with Therapeutic Equivalence Evaluations*, usually referred to as the "Orange Book."

In 2005, respondent, Teva Pharmaceuticals USA, Inc., acting through its Gate Pharmaceuticals division ("Teva"), filed an Abbreviated New Drug Application ("ANDA") seeking FDA approval for a generic donepezil product (the "Gate Product"). *See* 21 U.S.C. §355(j). Teva later amended this ANDA to include a certification under 21 U.S.C. §355(j)(2)(a)(vii)(IV) (a "Paragraph IV certification") that the five Eisai patents listed in the Orange Book with respect to Eisai's donepezil product were either invalid or would not be infringed by Teva's proposed generic product. The submission of this certification constituted an act of infringement of all five patents sufficient to support an infringement action by Eisai against Teva. 35 U.S.C. §271(e)(2).

Eisai sued Teva, but only for infringing the '841 patent. Eisai refrained from claiming infringement of the four other patents for reasons explained in the Federal Circuit's decision below. *See Teva Pharms. USA, Inc. v. Eisai Co., Ltd.*, 620 F.3d 1341, 1344-45 (Fed. Cir. 2010). Another generic company, Ranbaxy Laboratories Ltd. ("Ranbaxy") was the first generic company to submit a Paragraph IV certification as to those four patents. However, Ranbaxy had not made a Paragraph IV certification as to the '841 patent. Federal law rewarded Ranbaxy for being the first to challenge the other four patents with a lucrative 180-day period of "exclusivity" during which period the FDA would approve no other company to sell generic donepezil. *See* 21 U.S.C. §355(j)(5)(B)(iv). Under the provisions of 21 U.S.C. §355 in effect at the time, Ranbaxy's 180-day period of generic exclusivity would be triggered by the earlier of Ranbaxy's commencement of commercial sales or the entry of a court judgment that the four patents were either invalid or not infringed. *Teva v. Eisai*, 620 F.3d at 1344 & n.2.

Because it had not challenged the '841 patent, Ranbaxy could not obtain FDA approval to begin commercial sale until that patent expired in late 2010. As a result, Ranbaxy's 180-day exclusivity period, which blocked FDA approval of the Gate Product, could not begin to run until that expiration. Thus, even if Teva were correct that all five of Eisai's Orange Book patents were either invalid or not infringed by Teva's generic drug product, Teva could not launch the Gate Product because Ranbaxy, the first Paragraph IV filer as to four other patents, had not challenged the '841 patent. However, if Eisai had sued Teva on all five patents, and Teva obtained a favorable judgment on those four patents before the expiration of the '841 patent, that judgment would have triggered Ranbaxy's exclusivity period even though Ranbaxy itself could not take advantage of it because it had declined to challenge the '841 patent. If Ranbaxy's exclusivity had run before the expiration of the '841 patent, then when that patent did expire, Eisai would face competition not just from Ranbaxy for 180 days, but from multiple generic competitors simultaneously. The downward pressure on pricing from such competition could be dramatic.

Accordingly, Eisai declined to sue Teva on the other four patents, in the hope that the absence of any threat of an infringement suit on those four patents would preclude Teva from initiating a declaratory judgment action to obtain a judgment that would trigger Ranbaxy's exclusivity period. *See Teva Pharms. USA, Inc. v. Pfizer Inc.*, 395 F.3d 1324, 1338 (Fed. Cir. 2005). But in *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007), this Court recognized that federal courts could exercise subject matter jurisdiction over declaratory judgment actions in patent cases even in the absence of a threat of

litigation. *See id.* at 132 n.11; *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1345-46 (Fed. Cir. 2007).

Eisai also delivered to Teva a covenant not to sue on two of the four patents. Since Eisai had earlier disclaimed the other two patents outright, Eisai argued that the elimination of any possible liability for infringing any of the four patents precluded Teva from maintaining its declaratory judgment action. *See Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054 (Fed. Cir. 1995) (patentee's covenant not to sue destroys Article III jurisdiction over suit for declaration of invalidity and non-infringement).

However, in *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278 (Fed. Cir. 2008), *cert. denied*, 129 U.S. 1316 (2009), the Federal Circuit ruled that under the unusual circumstances created by the Hatch-Waxman Act, a generic drug company seeking a declaration of invalidity or non-infringement could satisfy the justiciability requirements articulated by this Court in *MedImmune*, even though the patentee had given a covenant not to sue on the patent-in-suit. The District Court in this case deemed *Caraco* not controlling and dismissed Teva's declaratory judgment action for want of subject matter jurisdiction.

On Teva's appeal from the dismissal, the Federal Circuit reversed, concluding that *Caraco* did control. Eisai suggests that this ruling was "a decision of wide-ranging significance to the pharmaceutical industry," Pet. at 3, but the Federal Circuit itself viewed this case as presenting a straight-forward application of its own precedent. *See Teva v. Eisai*, 620 F.3d at 1348-50.

Although the Federal Circuit in this case ruled that Teva could challenge the four patents-in-suit in order to obtain a judgment sufficient to trigger Ranbaxy's exclusivity period, time ran out on Teva before it could take advantage of the ruling. While Eisai's petition to the Federal Circuit for rehearing *en banc* was pending, the '841 patent expired and Ranbaxy launched its generic donepezil product. With that launch, Ranbaxy's 180-days of exclusivity commenced, and that left Teva with nothing to gain by continuing its declaratory judgment action. Because Teva's goal in the litigation was to trigger Ranbaxy's exclusivity period, the underlying patent dispute became moot, and Teva promptly filed a suggestion of mootness with the Federal Circuit.

Eisai moved the Federal Court to vacate its judgment. The Federal Circuit denied that motion without opinion, and the mandate issued. However, because Ranbaxy's launch had mooted Teva's claim for declaratory relief, on December 20, 2010, Teva filed a notice of voluntary dismissal of its complaint in the District Court on mootness grounds, as it was entitled to do under Fed. R. Civ. P. 41(a)(1) because Eisai had neither answered nor filed a motion for summary judgment. Teva's declaratory judgment complaint is thus no longer pending.

Eisai petitioned this Court for a writ of certiorari to review the denial of its motion to vacate. Because Teva no longer had a stake in the outcome, it waived its right to submit an opposition to Eisai's petition. However, this Court requested that Teva submit a response to the petition.

## REASONS FOR DENYING THE PETITION

**The Petition should be denied because Eisai lacks standing to seek resolution of the question presented.**

The parties agree that Teva's claim for declaratory relief became moot after the Federal Circuit's decision because Ranbaxy launched its generic donepezil product and thereby triggered its exclusivity period. Eisai argues that, as a result, the Federal Circuit was obliged to grant its motion to vacate its judgment reversing the dismissal of Teva's claim for a declaratory judgment. Eisai insists that this Court's decision in *United States v. Munsingwear, Inc.*, 340 U.S. 36 (1950), required the Federal Circuit to grant that motion, even as it acknowledges that there is a conflict in the circuits as to the proper application of *Munsingwear*.

However, this case does not present a suitable vehicle for resolving the question presented. Simply put, there is no justiciable case or controversy that would permit this Court to resolve whether the Federal Circuit properly denied Eisai's motion to vacate because Eisai lacks standing to seek a vacatur order from this Court.

It is well-settled that to seek relief from this or any other court, the party seeking relief

> "must have suffered an 'injury in fact' — an invasion of a legally protectable interest which is (a) concrete and particularized, and (b) 'actual or imminent, not "conjectural" or "hypothetical."' Second, there must be a causal connection between the injury and the

> conduct complained of — the injury has to be 'fairly ... trace[able] to the challenged action of the defendant, and not ... th[e] result [of] the independent action of some third party not before the court.' Third, it must be 'likely,' as opposed to merely 'speculative,' that the injury will be 'redressed by a favorable decision.'"

*Arizona Christian School Tuition Org. v. Winn*, 131 S. Ct. 1436, 1442 (2011) (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992)). Eisai cannot satisfy this standard. As explained below, the Federal Circuit's denial of Eisai's motion to vacate its judgment causes Eisai no actual, concrete injury, and an order from this Court directing the Federal Circuit to vacate its judgment will redress no such injury.

Eisai posits that the denial of that motion has "unfairly saddled" it "with a preclusive judgment of suspect merit in an important area of federal jurisprudence." Pet. at 4. Preclusion from litigating an issue in some future litigation does constitute an injury that may support standing. In *Munsingwear*, for example, the government requested that this Court vacate a moot judgment because rulings made in connection with that judgment precluded the government from pursuing a damages claim.[1] But Eisai does not identify any actual preclusive harm that the Federal Circuit's judgment causes, and no such harm exists.

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1. This Court denied the government's motion to vacate, but only because the government had slept on its rights, not because the government lacked standing to pursue the motion. 340 U.S. at 41.

The "preclusive judgment" with which Eisai is "saddled" is the Federal Circuit's ruling that the district court had jurisdiction over Teva's claim seeking a declaration that four of Eisai's patents are invalid or not infringed by Teva's proposed generic donepezil product. Eisai might have been harmed by an inability to contest that jurisdictional determination *if* Teva continued to press its claim for declaratory relief. However, it is perfectly clear that Teva is not pressing that claim and cannot press that claim because Teva no longer has standing to do so.

Nor is Eisai precluded in some future case from arguing that the Federal Circuit erred in this case or in *Caraco* in ruling that a generic drug company may be able to assert a declaratory judgment action even after receiving a covenant not to sue on the patents that are the subject of the action. This Court has recognized that the doctrine of issue preclusion does not apply to such pure legal issues. *See United States v. Moser*, 266 U.S. 236, 242 (1924) ("[*res judicata*] does not apply to unmixed questions of law. Where, for example, a court in deciding a case has enunciated a rule of law, the parties in a subsequent action upon a different demand are not estopped from insisting that the law is otherwise, merely because the parties are the same in both cases."). It is also black letter law that issue preclusion does not apply to an issue of law where the second action is "substantially unrelated" to the judgment giving rise to the preclusion, or a fresh consideration is "warranted in order to take account of an intervening change in the applicable law or otherwise to avoid inequitable administration of the laws," or "[t]here is a clear and convincing need for a new determination of the issue ... because of the potential adverse impact of

the determination on the public interest or the interests of persons not themselves parties in the initial action." RESTATEMENT (SECOND) OF JUDGMENTS §28.[2]

Once Ranbaxy launched its donepezil product, the declaratory relief that Teva sought in 2008 could no longer have any practical effect. Even if Teva could obtain a judgment that all four of the challenged patents were invalid or not infringed before Ranbaxy's exclusivity period expires on May 29, 2011 (180 days after Ranbaxy launched) — a highly questionable assumption — it would not accelerate the FDA's approval of Teva's ANDA by a single day. The combination of Eisai's patent disclaimers and covenants not to sue Teva have eliminated any exposure to patent infringement liability once Teva receives final FDA approval. Accordingly, even though the Federal Circuit concluded that there was subject matter jurisdiction over Teva's claim when Teva brought the claim in 2008, there is no subject matter jurisdiction over that claim today.

Thus, it no longer matters that Eisai might be precluded from denying that there was jurisdiction over Teva's claim for declaratory relief in 2008 because that claim no longer exists. Indeed, only days after the Federal Circuit's mandate issued, Teva's claim was dismissed on jurisdictional grounds —the same result that Eisai had earlier requested from the District Court — without Eisai having to take any action at all. There can be no

2. Eisai asserts that "[t]here was a reasonable likelihood that this Court would have granted certiorari to review the underlying judgment had it not become moot." Pet. at 31. That speculation may or may not be true, but it is irrelevant since the case did become moot.

future proceeding in which the issue on which Eisai fears "preclusion" can ever arise.

Accordingly, Eisai's inability to challenge the Federal Circuit's judgment or any of its findings cannot possibly visit any actual, concrete, particularized harm on Eisai, and an order from this Court vacating that judgment will remedy no such harm. Eisai, therefore, has no standing to request that this Court vacate that judgment.

This Court's decision in *U.S. Bancorp Mortgage Co. v. Bonner Mall Partnership*, 513 U.S. 18 (1994), is not to the contrary. In that case, this Court recognized that if a case becomes moot *after it has been accepted for review*, the Court retains jurisdiction to direct the proper disposition of the case in light of the changed circumstances, and in that context may direct that the decision accepted for review be vacated if such "extraordinary" relief is equitably warranted. *See id.* at 21-22. Once the Court has granted review, Article III does not prevent the Court from directing an orderly and equitable final disposition.

But here, the Court has not granted review. The question here is whether the Court should grant review at all. The indisputable fact is that *neither* party here has any concrete interest in the resolution of the question presented. Denying Eisai's Petition will leave Eisai in exactly the same position that it would face if the Court granted the petition and either directed that the Federal Circuit's judgment be vacated or declined to do so. Eisai has no standing to seek review and its Petition asks this Court to issue a purely advisory opinion. Article III does not authorize this Court to grant such a request.

## CONCLUSION

For the foregoing reasons, this Court should deny the petition.

Respectfully submitted,

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